K103043

510(k) SUMMARY

JAN - 7 2011

SUBMITTER INFORMATION

A. Company Name: Adapta Medical, Inc.

B. Company Address: 142 Talamine Court, Colorado Springs, Colorado 80907

C. Company Phone: 303 877 7056

D. Company Facsimile: 719 776 5045

E. Contact Person: Neil Burris

DEVICE IDENTIFICATION

A. Device Trade Name: PerfIC Cath™

B. Device Common Name: Urinary Catheter – Intermittent Catheterization

C. Classification Name: Urologic Catheter and Accessories

D. Device Class: Class II, per 21 CFR 876.5130

E. Device Code: EZD: Urologic Catheter and Accessories

IDENTIFICATION OF PREDICATE DEVICES

The PerfIC Cath™ is substantially equivalent to the SterileSure™ urinary catheter system, cleared to market under premarket notification K071496.

DEVICE DESCRIPTION

The PerfIC Cath™ is a straight single-use urinary catheter for intermittent use. The catheter is made of a simple piece of polyvinylchloride (PVC) tubing approximately 450 millimeters in length, with two (2) oval eyelet holes for intra-bladder urine collection at the proximal tip. The tip, to be inserted through the urethra, is sealed and rounded for patient comfort and safety. Liquid enters the catheter only via the lateral eyelets. The distal end of the catheter is connected to a PVC urine collection bag (volume = 900 ml ± 100 ml). Thus, the PerfIC Cath™ device facilitates its essential function by providing a channel for the drainage of urine from the bladder into a collection bag, via a straight piece of PVC tubing. Adapta Medical, Inc. supplies the PerfIC Cath™ in one size, 14 Fr.

K103043

INDICATIONS FOR USE

The PerfIC Cath™ is intended for use in adult male and adult female patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals who are unable to promote natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

COMPARISON TO PREDICATE DEVICES

The PerfIC Cath™ is substantially equivalent to the SterileSure™ catheter (K071496). The catheter is supplied sterile in a kit containing a pair of procedure gloves, a piece of gauze as absorbent material, and a benzalkonium chloride disinfecting wipe. Both of these urinary catheters are built with a reservoir of personal lubricant to ease catheter insertion and overall patient comfort. Both devices are supplied sterile; a protective sheath, over the portion of the catheter that may enter the body, aids in maintaining sterility during personal use of either the PerfIC Cath™ or predicate. Both are provided with urine collection bags having volumes greater than 500 ml. They are for use by persons with difficulty evacuating their bladders. SterileSure™ and PerfIC Cath™ are supplied with a 14 Fr catheter diameter size. The two (2) devices are substantially equivalent in form, fit and function.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

The PerfIC Cath™ meets acceptance criteria when tested for Cytotoxicity, Irritation, Dermal Sensitization, and Acute Systemic Toxicity. Adapta Medical, Inc. selected these biological reactivity tests based on the requirements listed in the harmonized standard ISO 10993-1:2009 for externally communicating devices, contacting tissue/bone/dentin, with a limited patient contact time.

PerfIC Cath™ kits are sterilized to a sterility assurance level of 10^{-6}, via electron beam radiation. Sterilization processes were validated in conformity with the ISO 11137 series of standards.

Bench testing confirmed that the PerfIC Cath™ catheter assembly met the device design specifications including package integrity and dimensions. Bench testing also confirmed substantial equivalency to the predicate with regard to mechanical integrity and the force required to advance the catheter.

CONCLUSION

The above statements establish substantial equivalence between PerfIC Cath™ and the SterileSure™ predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Adapta Medical, Inc.
c/o Neil Burris and Associates
Regulatory Affairs Consultants
4250 Grove Street
DENVER CO 80211

JAN - 7 2011

Re: K103043
Trade/Device Name: PerfIC Cath™
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: December 13, 2010
Received: December 15, 2010

Dear Mr. Burris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Benzalkonium Chloride (BZK) wipes or swabs, which are subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

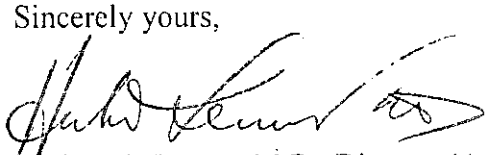
Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K103043

5. Statement of Indication for Use

JAN - 7 2011

Device Name: **PerfIC Cath™**

Indication for Use:

The PerfIC Cath™ is intended for use in adult male and adult female patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals who are unable to promote natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103043